CLAIMS

1. A method of delivering a biologically active agent to the central nervous system (CNS) of a mammal utilizing pathways that bypass blood-brain barrier comprising the steps of:

(a) establishing a source of the agent at a zone adjacent a mammal body surface area, the zones being selected from the group consisting of olfactory region, ocular region, brain surface, spinal cord, and intrabrain,

(b) establishing a radiant energy gradient from the source to CNS and maintaining the gradiant by energy supply to drive the agent directly from the source to and into the adjacent CNS region and within CNS essentially bypassing the mammal's blood-brain barrier,

the biological agent being selected of a species and size responsive to the radiant energy driving force and mobile within its selected pathway to and within CNS, but larger than sizes of agents that readily traverse blood-brain barrier.

2. The method of claim 1 wherein the olfactory system is used.

3. The method of claim 1 wherein the ocular (optic nerve) system is used.

4. The method of claim 1 wherein the brain is used.

5. The method of claim 1 wherein the spinal region is used.

6. The method of any of claims 1-6 wherein the radiant energy driving force is electrophoretic.

7. The method of any of claims 1-6 wherein the radiant energy driving force is magnetic.

8. The method of any of claims 1-6 wherein the radiant energy driving force is phonophoretic.

9. The method of any of claims 1-6 wherein the radiant energy driving force is electromagnetic.

10. The method of any of claims 1-6 wherein the radiant energy driving force is high frequency.

11. Apparatus usable in a non- invasive method for enhanced and controlled delivery of a biologically active agent to the central nervous system of a mammal and particularly a human being utilizing the olfactory pathways, the apparatus including:

(i) a first electrode insertable in the olfactory area of said mammal and said first electrode being a donor electrode that is constructed and arranged to be positioned in the olfactory area of a mammal,

(ii) a second electrode, the second electrode being a receptor pad electrode constructed and arranged to be positioned on or in proximity to the head of a mammal in one or more locations and constructed and arranged for co-operation with an energy source to establish a radiant energy gradient across at least a portion of the mammal's olfactory area central nervous system, and

(iii) means for energizing said first and second electrodes with an energy source providing a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the central nervous system via the olfactory pathways and thereby essentially circumventing the blood-brain barrier of the mammal.

12. The apparatus of claim 11, wherein said energy source is constructed and arranged to provide a type of energy selected from the group consisting of electric energy, magnetic energy, electromagnetic energy, high frequency waves and combinations thereof.

13. The apparatus of claim 1 wherein said first electrode means is of a design and shape, size or material to fit comfortably in a nasal cavity of a mammal and provides an intimate contact with the nasal mucosa in the olfactory area in order to enhance delivery of a biologically active agent via said olfactory area directly into the mammal's central nervous system, thereby essentially circumventing the mammal's blood-brain barrier.

14. Apparatus according to claim 11, wherein said first electrode is a reservoir-type iontophoresis electrode holding a supply of a biologically active agent in a formulation suitable for iontophoretic delivery through the olfactory mucosa and olfactory pathways to the central nervous system.

15. Apparatus in claim 14 wherein said reservoir holds a self-sealing membrane or valve to allow for in-situ refilling.

16. Apparatus according to claim 14, wherein said first electrode comprises an electroconductive part having electroconductive material selected from the group consisting of stainless steel, gold, silver, titanium, copper, zinc, graphite and metal salts (e.g. silver chloride).

17. Apparatus according to claim 14, wherein said reservoir of said first electrode means is formed of a polymer matrix containing an electroconductive filler material selected from the group consisting of a metal powder, powdered graphite and carbon fibers.

18. Apparatus according to claim 14, wherein said reservoir is constructed of material that is adapted to absorb, hold and release the biologically active agent.

19. Apparatus according to claim 14, wherein said reservoir comprises a polymeric material consisting of hydrophilic and hydrophobic matrix structure.

20. Apparatus according to claim 14, wherein said reservoir is made of a hydrogel that holds the biologically active agent.

21. A non- invasive method for enhanced and controlled delivery of a biologically active agent to the central nervous system of a mammal and particularly a human being utilizing the olfactory pathways that circumvent the blood-brain barrier, which includes the steps of:

administering a biologically active agent in the olfactory area of a mammal;

inserting a first electrode (s) containing an electrolyte in the anterior part of the nasal cavity;

applying a complementary electrode as a passive iontophoresis electrode on or in proximity to the head of the mammal in one or more locations and to establish a radiant energy gradient across at least a portion of the mammal's central nervous system; and

providing a potential gradient between the first and complementary electrode so that delivery of the biologically active agent is facilitated in a direction from said first electrode means directly into the central nervous system via the olfactory pathways and thereby essentially bypassing the blood-brain barrier of the mammal.

22. A method and device as claimed in claim 21 wherein said first electrode is positioned outside the nasal cavity.

23. A non- invasive method for enhanced and controlled delivery of a biologically active agent to the central nervous system of a mammal and particularly a human being utilizing the ocular pathway that circumvent the blood-brain barrier, which includes the steps of:

applying a first active iontophoresis electrode on an eyelid of said mammal,;

applying a second passive iontophoresis electrode on or in proximity to the head of the mammal in one or more locations and constructed and arranged for co-operation with an energy source to establish a radiant energy gradient across at least a portion of the mammal's central nervous system; and

providing a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the central nervous system via the ocular pathway and thereby essentially bypassing the blood-brain barrier of a mammal.

24. A method as claimed in claim 23, wherein an energy source selected from the group consisting of electric energy, magnetic energy, electromagnetic energy, high frequency wave sources and combinations thereof is used to provide a potential gradient.

25. Apparatus for enhanced and controlled delivery of a biologically active agent to the central nervous system of a mammal and particularly a human being utilizing the ocular pathway which includes the steps of:

applying a first active iontophoresis electrode on an eyelid of said mammal,;

applying a second passive iontophoresis electrode on or in proximity to the head of the mammal in one or more locations and constructed and arranged for co-operation with an energy source to establish a radiant energy gradient across at least a portion of the mammal's central nervous system; and

providing a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the central nervous system via the ocular pathway and thereby essentially bypassing the blood-brain barrier of the mammal.

26. An invasive method for enhanced and controlled delivery of a biologically active agent to the central nervous system of a mammal that circumvents the blood-brain barrier, which includes the steps of:

positioning a first electrode or donor iontophoresis electrode that is constructed and arranged to be positioned on the brain surface or intrabrain of a mammal and applying a receptor iontophoresis electrode within the mammal's head or on the exterior surface,

providing an energy potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the central nervous system thereby essentially bypassing t the blood-brain barrier.

27. Apparatus for enhanced and controlled delivery of a biologically active agent to the central nervous system of a mammal that bypasses the blood-brain barrier, which comprises:

a first electrode or donor iontophoresis electrode that is constructed and arranged to be positioned on the brain surface or internally of the brain of the mammal and a further receptor iontophoresis electrode in or outside the mammal's head,

means for providing an energy potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the central nervous system thereby essentially bypassing the blood-brain barrier.

28. A method and device for enhanced and controlled delivery of a biologically active agent locally of the spinal cord or another portion of the central nervous system of a mammal that circumvents the blood-brain barrier, which includes the steps of:

positioning a first donor iontophoresis electrode that is at or in close vicinity of the spinal cord of the mammal and applying a second receptor iontophoresis electrode in an internal complementary body location so that the two electrodes span the spinal cord;

providing a potential gradient between the electrodes so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the adjacent spinal tissue on another portion of the central nervous system thereby essentially bypassing the blood-brain barrier of the mammal; and

delivering said active substance into the spinal cord of said mammal.

29. Apparatus for enhanced and controlled delivery of a biologically active agent to a local spinal cord region or another portion of the central nervous system of a mammal that circumvents the blood-brain barrier, comprising:

positioning a first donor iontophoresis electrode that is at or in close vicinity of the spinal cord of the mammal and applying a second receptor iontophoresis electrode in an internal complementary body location ;

providing a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the adjacent spinal tissue or another portion of the central nervous system thereby essentially bypassing the blood-brain barrier of the mammal; and

delivering said active substance into the spinal cord of said mammal.

30. A phonophoresis method of delivering a biologically active agent to the central nervous system (CNS) of a mammal utilizing pathways that bypass the blood-brain barrier with minimal surgical intervention comprising the steps of:

(a) establishing a source of the agent at a zone adjacent a mammal body surface area, the zones being selected from the group consisting of olfactory region, ocular region, brain surface, spinal cord,

(b) establishing a radiant energy gradient from the source to CNS and maintaining the gradiant by energy supply to drive the agent directly from the source to and into the adjacent CNS region and thereby essentially bypassing the mammal's blood-brain barrier,

the biological agent being selected of a species and size responsive to the radiant energy driving force and mobile within its selected pathway to and within CNS, but larger than sizes of agents that readily traverse blood-brain barrier.

31. Apparatus for enhanced and controlled delivery of a biologically active agent to the central nervous system of a mammal and particularly a human being utilizing the olfactory pathways that circumvent the blood-brain barrier, the apparatus including:

a first electrode insertable in the olfactory area of said mammal and said first electrode being an donor electrode that is constructed and arranged to be positioned in the olfactory area of a mammal,

a second electrode, constructed and arranged to be positioned on or in proximity to the head of a mammal in one or more locations and constructed and arranged for co-operation with an energy source to establish a radiant energy gradient across at least a portion of the mammal's olfactory area central nervous system; and

means for energizing said first and second electrodes with an energy source providing a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the central nervous system via the olfactory pathways, essentially circumventing the blood-brain barrier of the mammal.

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